A Study of serrated polyps in families

As we grow older, small growths called polyps appear in the large bowel (also called the Colon). There are two main types; adenomas and serrated polyps.

Occasionally, a person will develop a specific type of serrated polyp. These are generally known as advanced serrated polyps and are associated with an increased risk of cancer of the bowel. In some cases, these advanced serrated polyps can run in families. In others, they are associated with cigarette smoking.

The aim of our project is to understand how these polyps form in members of a family. To do this we will look for alterations in genes inherited from your parents and shared with your relatives. An understanding of how genes act to make some of us susceptible to advanced serrated polyps will contribute significantly to prevention of bowel cancer in families.

Our study

The Genetics of Serrated Neoplasia (GSN) project has been in progress since 2005. During this time we have formed collaborations with investigators from several countries including Australia, New Zealand, Canada, Sweden, United States and United Kingdom, and have begun to enrol patients with advanced serrated polyps and their relatives.

We have obtained funding for the study from both National Australian and American government-based research bodies, as well as from the Cancer Council Queensland.

Regular updates on the progress of our study, including results and publications will be available on our website which you can access.

http://gsn.qimr.edu.au/assets/GSNInformationKit.pdf
**YOUR INVOLVEMENT AS A STUDY PARTICIPANT**

You are invited to take part in our study as a voluntary participant. Should you decide to do so, there are several things we will ask of you:

1) We will ask you to read this information kit. It consists of 5 pages and contains consent forms and a questionnaire.

2) We will ask you to complete a short consent form, and a one-page questionnaire regarding your personal and family history of polyps and cancers, as well as your smoking history.

3) We will also ask you to complete a further short consent form so that we may study your archived tissue blocks and pathology reports after the pathologist has completed the examination for your diagnosis. Tissue will be used to study gene mutations and pathology, and the tissue blocks returned to the pathology lab after we have sampled them.

4) We may ask you to provide a small blood sample. This will be approximately 40 ml which is equivalent to 2 standard tablespoon measures. Blood will be used to look for gene alterations.

**YOUR RIGHTS AS A STUDY PARTICIPANT**

We ask each participant to sign a consent form. In doing so, you agree to participate as described above after having the opportunity to read about the study and ask any questions which you may have. The following charter contains our obligations to you as a participant in our study:

1) **Your right to decide whether or not to participate.** Involvement in this study is entirely voluntary.

2) **Your right to decide how much involvement you wish to have.** You are free to withdraw from the study at any time. Your signature on a consent form does not commit you to remain in the study if you change your mind.

3) **Your right to privacy.** Your specimens and data will be stored as a numerical sample under secure conditions for at least 10 years. The identification of your information will only be available to the principal investigator and her senior staff.

4) **Your right to uncompromised treatment.** Participating in this study [or deciding not to participate] will not alter your doctor’s treatment in any way.

5) **Your right to know [or not know] of any clinical findings.** It is likely that your participation in our study will not produce significant benefit to you as an individual. However, in helping us learn how advanced serrated polyps form, you will be contributing to the prevention of these polyps in future generations. If by chance we discover information regarding any genetic risk of bowel cancer to you and your relatives, we will contact you, if you direct us to (see consent form) to ask whether you wish to attend a genetics clinic to receive the information.
Questions, Risks and Concerns

You may contact a member of the research team with any questions you may have regarding the study at any time.

There are several aspects of this study you need to be aware of as a study participant.

1) the giving of a blood sample may result in slight discomfort and minor bruising or bleeding. Your blood sample will be taken by trained personnel in private pathology laboratories and they will be able to deal with and mostly prevent these minor complications.

2) the genetic alterations we look at in blood and tissue are not genetic tests for cancer risk, and therefore will not be sent to you as a matter of routine. However, we occasionally find indications of a genetic risk by chance. If this happens, we will look at your consent form to see if you wish us to communicate the information to you via a genetic clinic.

3) participating in the study is not considered to be a genetic test for the purposes of health or life insurance

4) your information remains confidential, even to members of your family, unless you notify us in writing that you wish to share it.

Finally, your information remains confidential, even to members of your family, unless you notify us in writing that you wish us to share it with them.

There are no commercial interests associated with the study

Our study has been approved by the QIMR human research ethics committee (Approval number P912). If you have any concerns, please call the ethics officer on (07) 3362 0259.

Thank you

We thank you for your participation in our study. Each individual and their relatives make a unique contribution to our understanding of how risk of Bowel cancer is increased in some families. Studies such as these cannot proceed without the help of People such as you.

GSN Research Team

Principal Investigator: Dr Joanne Young (QIMR)
Senior Co-Investigators: Dr Susan Parry (NZ)
Dr Mark Jenkins (Victoria)
Mr Michael Walsh (QIMR)
Mr Daniel Buchanan (QIMR)
Dr Mark Clendenning (QIMR)
CONSENT FORM FOR STUDY PARTICIPATION

(PLEASE TICK EACH STATEMENT AGREED TO)

1) I have read the information or have had it read to me in my first language, and I understand what is required of me as a study participant [ ]

2) I have had an opportunity to ask questions about the study and am satisfied with the answers given to me [ ]

3) I agree to participate according to the requirements set out in the information brochure [ ]

4) I will be given a copy of the consent forms and information brochure to keep when I enroll in the study [ ]

5) I understand that my right to privacy will be protected at all times as outlined in the information brochure [ ]

6) I wish to be contacted if any information of clinical importance to my family is discovered during the study [yes] [no]

Participant(sign)………………………………………………….Date…………………………
Witness(sign)…………………………………………………………….Date…………………………

As the researcher, I have further explained the study to the participant and I am happy that they are aware of the procedures involved as well as their rights as a participant

Researcher(sign)…………………………………………………………….Date…………………………

ADDITIONAL CONSENT FOR TISSUE ACCESS AND STORAGE

1) I consent to the storage and use of my blood and tissue in the research project as outlined in the information brochure [ ]

2) I consent to the research project obtaining the pathology report, colonoscopy report and tissue blocks from the pathologist after the completion of the examination for my diagnosis [ ]

3) I consent to de-identified results from my samples being shared with other researchers in the consortium [yes] [no]

4) I consent to further research outside that outlined in this brochure being performed on my de-identified samples in the future [yes] [no]

Participant(sign)…………………………………………………………….Date…………………………
Witness(sign)………………………………………………………………….Date…………………………

As the researcher, I have further explained to study to the participant and I am happy that they are aware of the procedures involved as well as their rights

Researcher(sign)………………………………………………………………….Date…………………………
Name:_____________________________________________________________
Date of Birth:___/___/_____
Address:_____________________________________________________________
City:_________________ State_________ Postcode______________________
Email:_____________________________________________________________
Phone:__(____)_____________________________________________________

Have you ever smoked?__________________________________________________
How many years in total have you smoked?_________________________________
Average number of cigarettes per day?_____________________________________

Are you a current smoker?  Yes /  No
Have you ever had polyps or cancer of the bowel, or cancer at any other site?
________________________________________________________________________

Have any of your relatives [children, brothers, sisters, parents, grandparents, uncles aunts and cousins] had Bowel cancer?  Do you know how old they were? Don’t forget to tell us what side of the family [e.g. uncle on mother’s side]
________________________________________________________________________

________________________________________________________________________

Have any of your relatives had colon polyps? At what age?

________________________________________________________________________

Have any of your relatives had cancers of any other type?
At what age? ___________________________________________________________

What is the name of the doctor/s who treated you for your polyps or cancers? Which town/suburb is his/her practice located in?
________________________________________________________________________

Is there anything else you would like to add?
________________________________________________________________________

Sometimes we need to draw a family tree. May we contact you further if we need clarification of any of the above questions?  YES / NO

Would you prefer this to be by   post,    email   or    telephone?

If we phone you, what would be your preferred day and time?